DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pharmacare
C/O Mr. Paul Dryden
Promedic
24301 Woodsage Drive
Bonita Springs, Florida 34134

SEP 01 2010

Re: K101532
Trade/Device Name: NESSI OTC Spacer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVO
Dated: June 1, 2010
Received: June 3, 2010

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

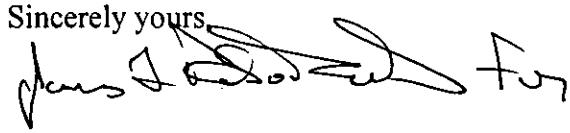
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101532

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: **NESSI OTC Spacer**

SEP 01 2010

Indications for Use:

The NESSI OTC Spacer is intended to be used to administer aerosolized medication from pressurized Metered-Dose Inhalers, which are over-the-counter (OTC), e.g., bronchodilator / epinephrine.

Prescription Use	**or**	**Over-the-counter use XX**
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 101532

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PharmaCaribe
3513 Di Leuca St.
Punta Gorda, FL 33950

Tel - (941) 505-0793
Fax – (941) 505-0718

Official Contact: W. Randolph Warner – Managing Member

Proprietary or Trade Name: NESSI OTC Spacer

Common/Usual Name: Spacer / Holding Chamber

Classification Name: Holding Chambers, Direct Patient Interface
NVO - CFR 868.5630

Predicate Devices: K091862 – PharmaCaribe NESSI (Rx) Spacer
Primatene Mist – OTC MDI

Device Description:

The NESSI is a spacer intended for use in the inhalation of medications which are provided by OTC MDIs. The device consists of a translucent housing a back piece and mouth piece or face mask.

It is a single patient, multi-use device.

Indications for Use:

The NESSI OTC Spacer is intended to be used to administer aerosolized medication from pressurized Metered-Dose Inhalers, which are over-the-counter (OTC), e.g., bronchodilator / epinephrine.

Patient Population: Any individual

Environment of Use: Home care, nursing homes, sub-acute institutions, and hospitals

Contraindications: None

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Attribute	510(k) K091862 PharmaCaribe NESSI Rx Spacer	Primatene Mist OTC MDI	Proposed PharmaCaribe NESSI OTC Spacer
Indications for Use	The NESSI Spacer is intended to be used by patients who are under the care of treatment of a licensed healthcare professional or physician. The device is intended to be used by these patients to administer aerosolized medication from pressurized Metered-Dose Inhalers, prescribed by a physician or healthcare professional.	MDI for use with asthma patients as a bronchodilator with epinephrine as the active ingredient	The NESSI OTC Spacer is intended to be used to administer aerosolized medication from pressurized Metered-Dose Inhalers, which are over-the-counter (OTC), e.g., bronchodilator / epinephrine.
Environments of use	Home care, nursing homes, sub-acute institutions, and hospitals	Home, hospitals and clinics.	Home care, nursing homes, sub-acute institutions, and hospitals
Prescriptive	Yes	No - OTC	No - OTC
Patient population	All	All	All
Single patient reusable	Yes	N/A	Yes
Used with mouthpiece or face mask	Yes	Mouthpiece only	Yes
Used with pressurized metered dose inhalers	Yes	N/A	Yes
Materials Common materials in contact with gas and fluid pathway	Yes	N/A	Identical to K091862
Performance testing	Particle characterization	Particle characterization	Particle characterization, compared to MDI with and without spacer plus Usability Study

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Performance Testing:

The NESSI OTC spacer was testing via Anderson Cascade Impactor testing for particle characterization and found to be equivalent and any differences did not raise any new safety or efficacy issues.

In addition a Usability study was performed to demonstrate that the instructions for use and ability of users to utilize the spacer were found to be appropriate for OTC designation.

Substantial Equivalence:

The NESSI is viewed as substantially equivalent to the predicate devices because:

Indications –
Similar to predicates - K091862 – PharmaCaribe NESSI Rx spacer but for use with OTC MDIs, i.e., Primatene Mist a bronchodilator / epinephrine which is sold OTC.

Technology –
Identical to predicate – K091862 – PharmaCaribe NESSI Rx spacer

Materials –
Identical to predicate – K091862 – PharmaCaribe NESSI Rx spacer

Environment of Use –
Identical to predicate – K091862 – PharmaCaribe NESSI Rx spacer

Patient Population –
Identical to predicates – K091862 – PharmaCaribe NESSI Rx spacer and Primatene Mist OTC MDI